

## **REMARKS**

### **Claim Amendments**

Claims 1-2, 6-10, 13, 17-18, and 20 are pending. In the Office Action of November 19, 2002, Claims 11-12, 14-16, 19, and 24-55 were withdrawn from further consideration by the Examiner under 37 C.F.R. § 1.142(b) as being drawn to non-elected inventions. Applicants have cancelled Claims 3-5, 13-16, 19, and 21-56 without prejudice and amended Claims 1, 2, and 20. Applicants submit that these amendments do not add any new matter. Accordingly, entry of the amended claims, and reconsideration of the application as amended, is respectfully requested.

### **The Outstanding Office Action**

In the final Office Action dated November 19, 2002, the Office required withdrawal of non-elected claims 11-12, 14-16, 19, and 24-55. The Office pointed out that upon allowance of a generic claim, applicant will be entitled to consideration of claims to additional species (i.e., 11-12, 14-16, 19, and 24-55). The Office rejected claims 1-10, 13, 17-18, 20-23, and 56 as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to use the invention 35 U.S.C. § 112 first paragraph. In addition, the Office rejected claims 1-7, 9-10, 13, 17, 23, and 56 as being anticipated under 35 U.S.C. § 102(e) by *Nacy et al.* (U.S. Patent No. 5,919,459).

### **Enablement**

The Examiner alleges that Claims 1-2, 6-10, 13, 17-18, 20-23, and 56 remain rejected under 35 U.S.C. § 112, ¶ 1 as containing subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or is most nearly connected, to use the invention.

Applicants submit that the presently pending and amended Claims 1-2, 6-10, 13, 17-18, and 20 are enabled. As amended, these claims are directed to methods of inhibiting an unwanted angiogenic condition in a mammal by administering an effective amount of a

modified angiogenesis associated receptor to the mammal, thereby causing an immune response against a molecule that induces angiogenesis in the mammal. Applicants submit herewith a Declaration under 37 C.F.R. § 1.132 of Daniel J. Hicklin, one of ordinary skill in the art and one of the co-inventors of the above-identified application. This Declaration demonstrates that, using guidelines set forth in the specification of the above-identified application, an immune response against an angiogenesis-associated molecule was induced in a mammal following administration to the mammal of a modified angiogenesis associated receptor.

Specifically, antigen presenting (AP) cells were harvested. These dendritic (AP) cells were pulsed with an angiogenesis associated receptor, FLK-1, thereby modifying the FLK-1 into FLK-1AP. This modified angiogenesis associated receptor was used to vaccinate mice exposed to Lewis lung carcinoma to induce an immune response against FLK-1, a molecule known to be barely detectable in normal endothelial cells, but known to be upregulated in endothelial cells in close proximity to tumors and also to induce tumor angiogenesis. The mice were vaccinated by either intravenous or intraperitoneal injection of the modified angiogenesis associated molecule, FLK-1AP, and then exposed to the Lewis lung carcinoma, namely the D122 cells. Visible tumors were removed and mice were sacrificed and lungs weighed in order to assess metastases. A control group of mice were vaccinated with dendritic cells alone. Mice vaccinated with the modified angiogenesis associated receptor, FLK-1AP, developed much smaller and far fewer tumors in the lungs than the mice vaccinated with just the dendritic cells or AP cells alone.

Accordingly, the disclosure contains sufficient information to enable one skilled in the pertinent art to make and use the claimed invention and, therefore, Applicants request that the rejections under § 112, ¶ 1 be reconsidered and withdrawn.

#### **Anticipation**

The Examiner alleges that claims 1-7, 9-10, 13, 17, 23, and 56 are unpatentable as anticipated by Nacy et al., U.S. Patent No. 5,919,459 ("the '459 patent").

Applicants respectfully traverse the rejection and maintain that the '459 patent does not anticipate any of the claims set forth in the above identified application. As discussed previously, the presently pending and amended Claims 1-2, 6-7, 9-10, 13, and 17 are directed to method of inhibiting an unwanted angiogenic condition in a mammal by administering an effective amount of a modified angiogenesis associated receptor to the mammal, thereby causing an immune response against a molecule that induces angiogenesis in the mammal. Unlike the present invention, Nacy does not teach administration of modified angiogenesis associated receptors. Instead, the '459 patent teaches active immunization with growth factor-containing compositions, which elicit the production of antibodies specific for growth factor when administered to a mammal, and passive immunization by administering antibodies specific for growth factors to a mammal. According to Nacy, growth factors are polypeptide growth factors and polypeptide angiogenesis factors. '459 Patent, col. 3, ll. 34-37. There is simply no teaching in the '459 Patent of inhibiting angiogenesis using the presently claimed modified angiogenesis associated receptors. Accordingly, each and every element of the present invention is not set forth in the '459 Patent and Applicants respectfully request that the rejection under § 102 be withdrawn.

**CONCLUSION**

In view of the foregoing remarks, Applicants respectfully submit that all of the presently pending claims are in condition for allowance and request that a timely Notice of Allowance be issued in this case. If the Examiner believes that issues may be resolved by a telephone interview, the Examiner is urged to telephone the undersigned at (212) 908-6277.

The Commissioner is authorized to charge any required fees that may be due, or credit any overpayment, to Deposit Account No. 11-0600.

Respectfully submitted,

Date: December 22, 2003

  
Kathryn M. Lumb (Reg. No. 46,885)  
Direct (212) 908-6277  
KENYON & KENYON  
One Broadway  
New York, NY 10004  
(212) 425-7200 (Telephone)  
(212) 425-5288 (Facsimile)  
**CUSTOMER NO. 26646**